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A PROSPECTIVE OBSERVATIONAL STUDY ON AVAILABILITY AND STORAGE OF VACCINES IN THE COMMUNITY PHARMACIES AT PARASSALA

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ABSTRACT

Background of The Study: The present study aimed to evaluate the availability and storage of vaccines in community pharmacies at Parassala. **Methods:** This is a Prospective observational study conducted at community pharmacies (in Parassala location). In this study, we analyse the availability and storage of vaccines in community pharmacies. Suitably designed Proforma is used to assess the availability and storage of vaccines. **Result:** From community pharmacy, as per the study criteria 27 samples are selected randomly from the accessible pharmacies from Parassala were enrolled in the study. This study aimed to analyze the availability and storage of vaccines in community pharmacies. **Conclusion:** In our study demonstrated that 27 samples are selected randomly from the accessible pharmacies from Parassala and the information's are collected from those pharmacies. From the data collected it was analysed that the distribution of air conditioner facilities is only 33%. The availability of cold chain maintained in various pharmacies is found to be 83%. According to the analysis from 27 pharmacies, majority of the pharmacies contain one pharmacist which is followed by two, three and four. From the study it was found out that out of 27 pharmacies 75% of pharmacist were qualified as D pharm, 17% were

qualified by both D pharm and B pharm and 8% were qualified by both B pharm and M pharm. According to the study it was found that out of 27 pharmacies the refrigerator facilities including the maintenance of temperature {2 to 8^0C} are followed by all of them {100%}.

INTRODUCTION

Pharmacy is the science and practice of discovering, manufacturing, dispensing, reviewing and monitoring of medications in order to ensure the safe, effective and affordable use of medications. Pharmacy serves as connection between all the health science, pharmaceutical science and natural science. The professional practice is now becoming more clinically oriented. The pharmacy practice can be classified as community or institutional pharmacy or clinical pharmacy. The pillar of a pharmacy is the pharmacist, who has a bunch of responsibilities. Pharmacists are responsible for the preparation of dosage forms of the drugs, such as tablets, capsules and sterile solutions for injection.

According to ancient Egyptians, the word pharmacy is derived from *ph-ar-maki*, which means the provider of safety and security. According to Greeks, the word pharmacy was taken from the word *pharmakon* which means drug and poison. The expert in the field of pharmacy is the pharmacist earlier referred to as the shamans, priests, healers, chemists and druggists. The birth and history of pharmacy began when the early human realized that the extracts of the leaves have medicinal values. From that day, humans started trying various plants on several injuries and diseases based on previous observations. It kept on continuing till the late of 18^{th} century. In the late 18^{th} century, people started experimenting with chemicals, which revolutionized pharmaceuticals. Scientists observed that some chemicals reacted differently at different temperatures. Pharmacy in India also goes back to very ancient past. The subject of ayurveda and yoga is considered to be very important in Indian pharmaceutical studies. The roots of ayurveda and yoga can be traced back to more than 5000 years. It has to be noted that in Indian culture, there is no difference between a pharmacist and a doctor. Therefore, it gives a solid base for all the ancient doctors in our country to try medicines they felt would suit the patient's body better. Indians far back in the past observed that the root cause for most diseases is viruses caused by the contact of dead animals. So, people in India started the practice of consuming vegetarian foods over non-vegetarian food. Today people appreciate this practice all across the world as this gives us immunity to certain diseases from birth. Diseases have haunted mankind since forever, and the need to find cures

has always been challenging. From using mud to chemicals, the history of pharmacy has been fascinating. The pharmacy also deals with various synthetic chemicals that can be used as pain killers and disease curing drugs. These drugs are manufactured using various chemicals, mixing them with herbal extracts. These combinations are done based on individual chemical behaviours in humans. One of the best-known antibiotics in the history of mankind is known as penicillin, discovered by Sir Alexander Fleming in 1928. It is not a myth that more than 75% of today's population must thank penicillin. Without it most of our parents and grandparents would get infections, and the population would have never reached the numbers it has today. Penicillin is an antibiotic that cures humans of a wide range of diseases. This was the pharmacies single answer to many questions and cures. Earlier people had no knowledge of the dosages that one had to take to avoid other side effects of the medicine. Today, we are aware of the medicines functioning in the human body, specific to the age and medical history of the patient.

A health care system without medicines seems unthinkable given that they are one of the most important tools we have to prevent illness and improve health. However, a lack of consistent access to medicines, poor quality of medicines and improper use are the main problems in many countries around the world. Having an understanding of why these issues happen and how to prevent and manage them is critical. Appropriate use of medicines in the pharmacy department is a multidisciplinary responsibility under the supervision of a qualified pharmacist and includes procurement, storage, preparation, and dispensing. The main responsibilities of a pharmacist include compounding and dispensing medicines and providing counselling to the patients. Proper procurement, storage, dispensing, and documentation of medicines are important aspects of pharmacy management. Large amounts of medicines are wasted during procurement, storage, distribution, and utilization. A pharmacy in India should maintain and follow standard operating procedures. A good dispensing environment is an important part of day-to-day pharmacy practice and includes staff, physical surroundings, and equipment. Most medical products are for internal use and require a clean, hygienic, and organized dispensing environment to prevent contamination. Proper environmental controls such as temperature, light, humidity, conditions of sanitation, ventilation, and segregation must be maintained, along with warehouses offering sufficient storage space. Warehouses should have sufficient storage space along with the necessary facilities to handle medicines efficiently and as per the guidelines. Storage must be secure, and fixtures and equipment used to store medicines should be constructed in such a way that

medicines are accessible only to designated and authorized personnel. Such personnel must be carefully selected. Safety is an important factor, and proper considerations should be given to the safe storage of poisons (disinfectants or other chemicals not meant for human use) and inflammable compounds. A pharmacy should have all the necessary equipment required for good drug-dispensing practices.

Public health facilities remain the main source of healthcare services for the majority of individuals. The rational use of medicines in public health facilities is directly dependent on pharmacy services. Drug storage is the important responsibility of pharmacists. Therefore, adequate methods to assure that these responsibilities are met must be developed and implemented. The pharmaceuticals are to be stored under conditions that prevent contamination and deterioration. The stability of product retains within the specified limit, throughout its period of storage and use. Precautions that should be taken in relation to the effects of the atmosphere, moisture, heat and light are indicated. Storage of the pharmaceutical products is one of the fundamental concerns in patient care. The conditions under which pharmaceutical products are manufactured and stored can have a major impact on their quality. High temperature and relative humidity (RH) are the most important factors involved in drug degradation. Factors such as temperature, humidity, air quality, time and production process characteristics can all have a significant impact on the final quality, and therefore the sale ability, of a product or batch of products. For many products requiring storage in cool conditions, refrigeration plant is widely used, which needs to be carefully monitored to ensure that the correct temperatures are maintained. Stock must be stored in appropriate and auditable environmental conditions.

Appropriate conditions of light, humidity, ventilation, temperature and security should be ensured. All medicinal products must be stored in accordance with the manufacturer's directions and within the terms of product authorizations. Pharmacy stock should be stored under suitable conditions, appropriate to the nature and stability of the product concerned. Particular attention should be paid to protection from contamination, sunlight, UV rays, moisture, atmospheric moisture and extreme temperatures. During storage, medicines should be retained in the manufacturer's original packaging. Good storage practice is applicable in all circumstances where pharmaceutical products are stored throughout distribution process.

STORAGE OF MEDICINES

Medicines are items, which require careful, scientific and systematic storage. Heat, light, moisture and air can cause serious damage to the properties of drug. The shelf life of a drug is very much influenced by its storage conditions. The expiry date specifies is based on the assumption that the drug will be stored under the required conditions. In most cases the storage conditions will also be shown on the label. Good storage practice helps improve quality, efficacy and economy of the establishment. It also helps to enable the smooth and complaint free working of the storage and speedy execution of works avoiding delays and bottlenecks in office work and reduces the chance of error and help for quick identification of items, better stock control and proper accounting.

The Drug and Cosmetic rule 1945, specifies the importance of storage conditions for various categories of drugs. It says that if Polio vaccine is stored at -20ºC, it will have a shelf life of 24 months. The same item will have shelf life of only 6 months if stored at 0ºC and will become 3 months if stored at 4ºC. One can imagine the fate of such products if keep at room temperature. Vaccines in particular must be kept at precisely controlled temperature from the time of manufacture to the time of administration. Cold chain problems during ware transportation are the frequent problems faced in the preservation of vaccines potency. Measles vaccines, when stored at 2 to 8ºC maintains its potency for at least 2 years while the same vaccine if exposed to a temperature of 40ºC loses its potency within 24 hours.

Fig No.1: Vaccine Administrations.

Factors affecting potency of drugs during storage

Drugs are often designated as useful poisons. It signifies the point that most of the potent drugs become highly toxic or dangerous if not properly handled and stored. Modern

medicines are formulated by using powerful chemical compounds. Every drug has a shelf life, which is the period between date of manufacture and date of expiry. During the shelf-life period, a medicine is expected to retain its potency, safety and action. The expiry date and shelf life of the medicine is very much dependent on the specific storage conditions. If the storage conditions are adhered, there is no guarantee that the product will be useful even for a part of the normal duration of its shelf life. If not properly stored, a drug product can become ineffective, toxic or even fatal within its normal shelf-life period. This is the reason why often vaccines and many other biological products become toxic before their expiry date.

Some drugs are highly sensitive to heat, light, Moisture or even atmospheric air. Some others are moderately sensitive to these factors. The expiry date of a drug shows the period of life of the drug, and till that date the drug is expected to maintain at least 90 percent of the labelled claims, unless it is scientifically stored during the entire period. Each material has its own storage requirements and knowledge is necessary as to how and where they are stored. Only if we are aware of the properties and characteristics of the material, we can handle and store them properly.

The pharmaceutical manufacturers label their medicines with a wide variety of storage conditions. Some of the important storage conditions prescribed by the Indian pharmaceutical manufacturers through the labels of their products are noted below.

- Keep in a cool dry place.
- Keep in a cool dark place.
- Keep in a cool place (do not freeze).
- Protect from heat and light.
- Store below 25ºC.
- Store at 2ºC to 25ºC.
- Store between 15ºC to 25ºC.
- Store away from sunlight.
- Store below 30ºC protected from moisture.
- Store in a cool dry place protected from light.

Studies have shown that 60 to 70 percent of the ethical formulations in Indian markets bear a label direction “keep in a cool place” or “To be stored in a cool place”. We had seen that in order to provide a cool place, air conditioning of the premises is essential. For providing

"cool place" refrigerators and walk in coolers are needed. Frost-free refrigerators are best suitable for storage of medicines under "cold place". Shelves (closed type) cupboards, drawers etc. are used to provide dark places and for the storage of medicines which are to be protected from sunlight. If there is a "keep in a cool place", direction on the label, it invariably shows that the drug can be used till its expiry date only if it is stored in a cool place. If such a drug is kept at room temperature, its potency may be lost much before the expiry date noted on the label.

Storage Conditions

Only very few medicines can be properly stored at room temperature. The rate of decay or deterioration becomes faster with rising temperature of storage. The deterioration will minimize when the drug is in a dry state and if such drugs are stored at cool temperatures the deterioration can further reduced.

The first edition of Indian Pharmacopoeia did not specify the various storage conditions prescribing the temperatures or their range. Now the current edition of the pharmacopoeia specifies the various storage conditions. The rules under the drug and cosmetics act also specifies the various storage conditions. The 1996 edition of IP specifies the storage conditions as.

- Cold place
- Cool place
- Room temperature
- Warm place
- Excessive heat

Cold Place

Cold place is a place where the temperature is not exceeding 8^0C and usually between 2^0C and 8^0C. A refrigerator is a cold place in which the temperature is maintained thermostatically between 2^0C and 8^0C. There are a large number of drugs, which are sensitive to even controlled room temperature. Such drugs are to be kept either in a "cool place" or in a "cold place". Pharmacopoeias like IP, USP, BP and the BPC agree with the American standard for 'cold place' as given in their national formulary. According to the National formulary of America, cold place is one having a temperature not exceeding 8^0C. Refrigerator is a cold place where temperature is maintained thermostatically between 2^0C

and 8^0C and freezer is also a cold place where temperature is maintained between -20^0C and -10^0C.

Special attention should be given to the storage of drugs, which require a low temperature for retaining their potency. Some of these drugs have to be stored between 2^0C to 10^0C and drugs which are required to be stored between 2^0C to 8^0C or between 2^0C to 10^0C include sera in general, vaccines in general and glandular preparations. All drugs with a label direction 'keep in a cool place' should be kept at the above temperature range. The schedule P of the drug rules gives the list of drugs, which require special storage conditions like "cold" or "cool", below 5^0C etc. It is to be noted that drugs like oxytocin injection, insulin preparations etc. will lose their potency within hours if kept at high temperatures. Drugs like insulin and certain vaccines should not be allowed to freeze as they contain proteins, which will be denature on freezing and subsequent melting. Hence freezing will harm the potency of such items. Care should be taken to see that such drugs are not kept in the freezing compartment of the refrigerator.

Cool Place

A cool place is an environment where the temperature is between 8^0C to 25^0C. An article for which storage in a cool place is indicated may, alternatively, be stored in a refrigerator, unless otherwise specified in the individual monograph. Drugs like antibiotics, hormone preparations, vitamins, liver preparation, etc. are required to be stored in a cool place storage condition are invariably shown on the outer package of the drugs. Such detail should be checked and be compare by the pharmacist in charge of the store. Air-conditioned storage accommodation should be provided for this purpose. A record of the maximum temperature in the cool place should be maintained. A recording thermometer can be used for this purpose. The record should be checked and signed by the pharmacist in charge at least three times in a day. The space of the AC room should be adequate considering the maximum stock of the drug likely to be purchased by the hospital during one year.

In order to maintain the stability, potency, efficacy and safety of the drugs and other medicinal items, all hospital pharmacies and community pharmacies should have a cool place. All items like antibiotics, capsules, etc. having labelled directions to be kept in a cool place should be kept in a cool place only, the cool place can be provided by installing air conditioners of suitable capacity like 1.5 tons cap. The cool place should have a false ceiling with clean painting. The floor should have vinyl carpet laid. An analysis of the drug products

available in the Indian market which are generally used in the hospitals shows that 60-70% of the drugs are required to be stored in a cool place.

Room temperature

The room temperature is the temperature prevailing in a working area. India being a tropical country there will be much variation in the room temperature throughout the year.

Warm

A warm place is an area where temperature is between 30ºC to 40ºC.

Excessive heat

Excessive heat is any temperature above 40ºC. In addition to the above storage conditions the USP 1995 edition specifies 'controlled room temperature' and 'freezer'.

Controlled room temperature

According to the USP controlled room temperature is a temperature maintained thermostatically that encompasses the usual and customary working environment of 20ºC to 25ºC. However, in India, the controlled room temperature is generally taken as 15ºC to 30ºC. An article, for which CRT is directed, may alternatively be stored in a refrigerator unless otherwise specified by the individual monograph or the product label. If the storage conditions are not specified on the label, it is to be understood that the drug has to be stored at 'a controlled room temperature'.

Storage under non-specific condition

Where non-specific direction is indicated in the individual monograph, it is to be perceived that the storage condition include protection from moisture, freezing and excessive heating.

Freezer

Freezer is a place in which the temperature is maintained thermostatically between -20ºC to -10ºC.

The schedule 'p' of the drugs and cosmetics rules 1945, specifies the life period of many drugs when kept under specific storage condition. Th significance of the storage conditions can well be understood from this schedule. Liquid plasma has been given a life of 24 months when kept in cold place where as frozen plasma has a life of 60 months when stored in deep freeze. The influence of temperature on certain pharmaceutical preparation can well be

understood from the variation of the life period of polio vaccine under different storage conditions. Polio vaccine is given a life period of 24 months when stored at -20ºC which will be reduced to 6 months at 0ºC and 3 months at 4ºC.

Protection from freezing

In the case of many items, in addition to the risk of breaking of container, freezing also results in loss of strength or potency or in destructive alteration of the characteristics of the contents. In such cases, the label on the container should bear an appropriate instruction to protect from freezing.

CONSTRUCTION OF A COLD ROOM

For the storage of drugs to be kept in cold place in large quantities, a separate room, maintained at the required temperature range called "cold room", is highly used. A cold room can be constructed as per the needs with less expense and more convenience. A little used corner of the basement storage premise with required area is an ideal place that can be used for the construction of the cold room. If windows are present, they should be closed double passed and tightly sealed. Alternatively, the windows can be removed and the opening should be bricked up. Electric fixtures should be installed with controlling switches on wall outside the room and near the entrance. The necessary additional walls inside the room can be constructed of concrete, bricks or wood stood with aluminium or other suitable insulation materials. The sides of the wall should be cement plastered or finished with other material. The doors should be tight provided with the good automatic door closer.

An electric motor-driven air-cooled compressor unit with a remote blower type cooling coil will provide a necessary refrigeration. This unit should be installed with necessary thermostat and expansion valve required to maintained the desire temperature range. The blower is mounted in the cold room. To it, a small waste line is installed to drain away the condensate, which collects on the refrigerator coil. The compressor may be installed outside the cold room in order to conserve space with in. The size of the cold room will determine the capacity of the refrigeration unit to be installed. A room with 10' x 10' x 10' dimension may require 1.5 ton of refrigeration to maintain required temperature range. Once constructed, the room may be equipped with necessary shelving, storage bins, cabinets and workbenches. A recording thermometer should be provided and the temperature should be noted 3-8 times with in period of 24 hours. Instead of constructing a cold room, "walk-in-coolers" with necessary operating temperature can be procured and installed.

Cold Chain

Drugs like vaccines and other biological preparations lose their potency quickly if stored or kept under high temperatures for some time. Such drugs often cause problems at the time of transportation from one place to another as in the case of supply from the manufacturing premises to the consumers or hospitals or dealers in a faraway place. This is a serious problem in the case of tropical countries like India where high ambient temperature are very common. The cold chain is an arrangement used to protect the temperature sensitive drugs from the exposure to atmospheric temperature during transportation from one place to another. The cold chain from the point of view of drug storage represents the arrangement of facilities used to keep drugs at low temperatures from the manufactures end to the uses end. Such cold chain systems are in operation in countries like India, Bangladesh, Burma, Indonesia, Liberia, Pakistan, Philippines, Thailand, Uganda and several South American countries. Organizations like WHO, UNICEF etc. help the countries to install and improve cold chain facilities by encouraging them to develop a wide range of cold chain equipment suited to the needs of the countries.

An effective system of temperature monitoring and recording is vital for the cold chain in order to minimize failure of cooling. Commonly used temperatures monitoring equipment's in cold chain consists of thermometers like two channel clockwork temperature recorders with alarm switching for use in cold rooms, dial thermometers with maximum pointer and alarm switching for use in large vaccine refrigerators or freezer and dial thermometers with maximum or minimum pointer for use in vaccine refrigerators or freezers located in peripheral areas. The 2-channel clockwork temperature recorder with alarm and dial thermometer with maximum pointer and alarm are developed specifically for use in tropical climates and for area with intermittent electrical supply. The UNICEF warehousers use the dial thermometers with maximum or minimum pointer. Vaccines deteriorate at a rate determined by both time and temperature. It is therefore important to have some record of the handling history off any given package. Time temperature tags are used to monitor the standard of vaccine handling during the process of transportation to the peripheral areas where vaccine is used.

Electricity failures and fluctuating voltages are common features of electricity supplies in many developing countries and these factors in addition to tropical conditions, often lead to high internal temperatures in front of opening domestic refrigerators. The frequent voltage

fluctuations damage the compressors and shorten its working life. Above all, the standard of construction of domestic refrigerators is less than adequate to provide a controlled temperature between 4^0C and 8^0C required for vaccine storage in tropical climates. Commercial chest freezers converted to act as vaccine refrigerators have the advantage like better insulation, smaller temperature difference in the storage area. Better configuration of space for storage of vaccine packages and less escape of cold air through the top opening. Suitably designed chest freezers can keep the vaccine cool over considerable period when the current fails or voltages are low. Tests have shown that when ambient temperatures are held at 43^0C, vaccine storage temperatures can be maintained with only 8 hours of electric supply in each 24-hour cycle. The power consumed in a 24-hour period per unit volume in stores is lower than that of standard domestic refrigerator and security for vaccine stored is enormously increased.

Vaccine refrigerator, which can operate without electricity, are also used in 'cold chain'. Performance tests on front opening refrigerators opening on kerosene have shown that such refrigerators are useful if the ambient temperature is below 40^0C. Units operating on liquid propane gas are easier to manage and more reliable. They require less maintenance, but supply of gas cannot always be relied upon. Solar refrigerators and icepack freezers are also in use. Portable refrigerator equipment like Peltier effective refrigerator or freezer, rotatory type compressor refrigerator, swing type compressor freezer, absorption type refrigerator, etc. are also used in the cold chain. They usually have a capacity ranging from 5 to 30 liter manufactured mainly for camping market.

Portable equipment's are used for static storage of small quantities of vaccines, glandular preparations like insulin and similar items. And for transport of such drugs over long distances in vehicles. Cold boxes for transport of vaccines between stores and vaccines carriers are also used in cold chain establishment.

The vaccine carriers are light, robust and relatively low in cost and have a cold life of about 36 hours at outside temperature up to 43^0C. They usually have a capacity of 1.5 liters. Ice and ice packs are constantly needed for cooling insulated vaccine container of all kinds and for storing and transporting vaccines in rural areas. Absorption type domestic refrigerators in areas without electricity male ice with great difficulty and very slow rate. In the late 1970s, UK developed icemakers, which can easily overcome this problem.

The maintenance of vaccines, glandular drugs like insulin, at a safe storage temperature during transport from manufacturer to user destination depend on the standard of the insulated packing used. In practice, standards vary widely and many vaccines, insulin preparations and similar drugs are transported with an insufficient safety marketing to guard against possible delays. The manufacturer should inform the receiving parties well in advance about the arrival of the drugs that require cold storage, so that they can make suitable arrangements to take delivery of the consignment immediately on reaching the station. The cold chain arrangements are essential for the proper transport and storage of drugs like vaccine and biological products in order to protect their potency and ensure their quality.

REVIEW OF LITERATURE

1. **Dinesh K. Meena, Mathaiyan Jayanthi, Kesavan Ramasamy, Mahalakshmi Thulasingam** conducted a study on medicine storage and dispensing facilities in public health care pharmacies of **Puducherry**, India and published in the year 2022. This study was conducted to assess the storage and dispensing facilities of medicines in public healthcare pharmacies of **Puducherry**, province in south India. This study concluded that in **Puducherry**, pharmacy services are provided by qualified and experienced pharmacists. Although most of the surveyed pharmacies had all the required infrastructure and equipment facilities, few pharmacies need to improve their facilities to promote good drug-dispensing practices.
2. **Ram K. Panika, Pankaj Prasad, Sunil Nandeshwar** conducted a study on evaluation of vaccine storage and cold chain management practices during intensified mission Indradhanush in community health centers of Tikamgarh district of Madhya Pradesh and published in the year 2019.This study was done to assess the cold chain management and vaccine storage practices in Tikamgarh district of Madhya Pradesh. This study concluded that: Proper vaccine storage and management of cold chain system is essential for immunization. In order to improve quality of immunization services there is a need of space, temperature monitoring and regular defrosting with record keeping and regular training of cold chain handlers to keep their knowledge and skills updated
3. **Adeel Arsalan, Syed Baqar Shyum Naqvi, Azfar Iqbal, Osama Shakeel** conducted a study on Temperature Monitoring of Vaccines' Storage Compartments in Different Health Centres and Pharmacies at Karachi, Pakistan and published in the year 2014.The main aim of the present study was to find out vaccines' storage compartment temperature

in different private clinics, hospitals, and community pharmacies in Karachi, Pakistan. The study concluded that it has been found due to lack of knowledge,
insufficient training, importance of cold chain, and above all shortage and/or breakdown of power supply have been played an important role.

4. **Anna Kowalczyk, Alexandre Wong, Kevin Chung** conducted a study on patient perceptions on receiving vaccination services through community pharmacies. The objective of the study was to ascertain the perceptions of patients about receiving vaccinations through community pharmacies. The study concluded that Polish patients participating in the study have a positive attitude towards the implementation of vaccination services in community pharmacies as an effective way of combating infectious diseases.
5. **Albert T Bach, Jeffery A Goad** conducted a study on the role of community pharmacy-based vaccination in the USA: current practice and future direction. The aim of the study was to establish pharmacist role in immunization practise that has been desc2ribed as serving in the roles of educator, facilitator and immunizer. The study concluded that challenges that may need to be addressed are improvements in communication and continuity of care between community pharmacist and the patient centred medical home.
6. **Maria Lampasona, Luca Pantaleo** conducted a study on the role of pharmacies in immunization programs and health promotion. Aim of study was to analyse the involvement of pharmacist and pharmacies in vaccination campaign to confirm the professional role played by them. The study concluded that the involvement of community pharmacist in vaccination campaign are irreplaceable one.
7. **Nugroho Agung Pambudi et al** conducted a study on vaccine cold chain management and cold storage technology to address the challenges of vaccination programs. The aim of the study was to point out the major challenges of vaccination programs associated with vaccine cold chain management and cold storage facilities. The novelty of the study is to thoroughly explore cold storage technology for a faster and more comprehensive vaccine distribution hence it is expected to be one of the reference and inspiration for stakeholders.
8. **Alexandre Chadi et al** conducted a study on vaccine promotion strategies in community pharmacy addressing vulnerable populations: a scoping review. The purpose of this study is to describe how vulnerable communities are targeted in community pharmacies. The study concluded that pharmacists prioritize life cycle and clinical vulnerability at the expense of narrowing down the definition of vulnerability. Some vulnerable groups are

also under targeted in pharmacies. A wide variety of promotion strategies are available to pharmacies in order to overcome the specific barriers experienced by various groups.

9. **Randall C. Burson et al** conducted a study on community pharmacies as sites of adult vaccination: A systematic review. The aim of this systematic review was to assesses the feasibility, acceptability and effectiveness of community pharmacies as sites for adult vaccination. The study concluded that pharmacy-based immunisation services have been facilitated by state regulatory changes and training programs that allow pharmacists to directly provide vaccination.
10. **Tatenda T. Yemeke et al** conducted a systematic review of the role of pharmacist in vaccination services in low- and middle-income countries. The objective of the study was to identify and synthesize evidence on pharmacist's role in offering vaccination services in LMICs. The study concluded that the pharmacists have the potential to play an important role in increasing access to vaccines and improving coverage, yet evidence of their role in vaccination remains limited across LMICs. Greater documentation of pharmacist's involvement in vaccination services in LMICs is needed to demonstrate the value of successful integration of pharmacists in immunization programme.
11. **Fiona Ecarnot et al** conducted a study on pharmacy-based interventions to increase vaccine uptake: report of a multidisciplinary stakeholders meeting. The study concluded that a range of barriers to vaccine uptake have been identified, affecting all target groups, and in various countries and health care settings. Ease of accessibility is a potentially modifiable determinant in vaccine uptake, and thus, improving the diversity of settings were vaccines can be provided to adults, for example by enabling community pharmacists to vaccinate, may increase the number of available opportunities for vaccination.
12. **David M Dairo et al** conducted a study on factors affecting vaccine handling and storage practices among immunization services providers in Ibadan, Oyo state, Nigeria. The objective of this study was to assessing the factor associated with vaccine handling and storage practices. The study concluded that regular training is recommended to enhance vaccine handling and storage practices.
13. **Anika Thielmann et al** conducted a study on visual inspection of vaccine storage condition in general practice: A study of 75 vaccine refrigerator. The aim of this publication is to assess the quality of vaccine refrigerator management in general practice. The study concluded that we identified a large number of avoidable vaccine storage errors. Effective strategies, example web-based program, to improve vaccine storage condition in general practices are needed.

AIM AND OBJECTIVES

Aim

To study the availability and storage of vaccines in community pharmacies at Parassala.

Objectives

- To assess the availability of vaccines in community pharmacies.
- To assess the storage of vaccines in community pharmacies.
- To assess the maintenance of cold chain in community pharmacies

PLAN OF WORK

Phase 1

- Literature survey.
- Preparation of study protocol.

Phase 2

- Design of survey form.
- Data collection through survey form.

Phase 3

- Statistical analysis.
- Report submission.

METHODOLOGY

STUDY PROJECT

The duration of study is for 6 months.

STUDY SITE

It is the study conducted in community pharmacies in and around Parassala.

STUDY DESIGN

This is a community based prospective observational study.

SAMPLE SIZE

The research question is the facilities of the pharmacy in the parassala. The preparation of the facility available in the pharmacy is 80% and the level of significance is 5% and power of the study is 80%. The acceptable error is 15%.

Sample size (n) is calculated by the formula given by,

Formula

$N = Z^2 \alpha \ P\frac{(1-P)}{d^2}$

Were,

Z α = Value of 5% level of significance

n = sample size

d= margin of error

Acceptable level of significance 5% = 1.96

Power of the study 80% = 0.84

The margin of error of 15% = 0.15

Sample Size, (n) = $(1.96)^2 \times \frac{80\times20}{(0.15)^2}$ = 27

Sample Size (n) = 27

DATA COLLECTION

One time survey was conducted in the community pharmacies that are randomly selected from Parassala. Then the data were collected and analyzed accordingly.

STUDY PROCEDURE

- A survey form was prepared to collect information from the available pharmacies in and around Parassala.
- The availability of vaccines in various pharmacies were collected via the survey form.
- Maintenance of storage facilities were analysed.
- At the end the overall analysis of the collected data was carried out.

DATA ANALYSIS

Data were entered in Microsoft excel. Data were separately analyzed for different community pharmacies in and around Parassala. Availability of various facilities in the community pharmacies were determined. Data were analyzed using Microsoft excel.

OBSERVATION AND RESULT

From community pharmacy, as per the study criteria 27 samples are selected randomly in and around parassala. This study aimed to analyse the availability and storage of vaccines from community pharmacies.

DATA COLLECTION FROM SURVEY

Sl No:	Pharmacies	Type of Vaccines	Temperature maintanance In refrigerator	No: of pharmacist	Availability of ac in various pharmacies	Availability of cold chain in pharmacies	Qualification of Pharmacist
1.	Pharmacy 1	Tetanus, Antirabies, Adenovirus	2 TO 8^0C	2	NO	YES	D Pharm
2.	Pharmacy 2	Tetanus, Antirabies	2 TO 8^0C	1	NO	YES	D Pharm
3.	Pharmacy 3	All Type Vaccines	2^0C	4	NO	YES	B Pharm And D Pharm
4.	Pharmacy 4	Sub Unit Type Vaccines	2 TO 8^0C	4	NO	NO	D Pharm
5.	Pharmacy 5	Measles, Mmr Hepatitis B	2 TO 8^0C	1	NO	YES	D Pharm
6.	Pharmacy 6	Tetanus , Mmr	2^0C	3	YES	YES	B Pharm And M Pharm
7.	Pharmacy 7	Vetenary, Human Vaccines	2 TO 8^0C	2	YES	YES	D Pharm
8.	Pharmacy 8	No Vaccines	2 TO 8^0C	5	YES	NO	D Pharm And B Pharm
9.	Pharmacy 9	Tetanus Vaccine	2^0C	3	NO	YES	D Pharm, B Pharm, M Pharm
10.	Pharmacy 10	Hepatitis B, Mmr, Measles, Hepatitis A	2 TO 8^0C	1	NO	YES	D Pharm
11.	Pharmacy 11	Tetanus	2 TO 8^0C	1	YES	YES	D Pharm
12.	Pharmacy 12	Subunit Type Vaccine	2 TO 8^0C	3	NO	YES	D Pharm
13.	Pharmacy 13	Measles, Tetanus	2 TO 8^0C	2	YES	YES	Both Are D Pharm
14.	Pharmacy 14	Mmr, Tt, Anti Rabies	2 TO 8^0C	2	YES	YES	D Pharm
15.	Pharmacy 15	No Vaccines	2 TO 8^0C	1	NO	NO	D Pharm
16.	Pharmacy 16	Mmr,Tt	2 TO 8^0C	3	NO	YES	2 Bpharm And One D Pharm
17.	Pharmacy 17	Tt, Antirabies	2 TO 8^0C	3	NO	YES	D Pharm
18.	Pharmacy 18	No Vaccine	2 TO 8^0C	1	NO	NO	D Pharm
19.	Pharmacy 19	Subunit Type	2 TO 8^0C	2	NO	YES	D Pharm

		Vaccines					
20.	Pharmacy 20	Tt	2 TO 8^0c	1	NO	YES	D Pharm
21.	Pharmacy 21	Subunit Types	2 TO 8 ^{0}C	2	NO	YES	D Pharm
22.	Pharmacy 22	No Vaccines	2 TO 8^0C	1	NO	YES	D Pharm
23.	Pharmacy 23	Tt, Antirabies	2TO8^0C	3	NO	YES	D Pharm
24.	Pharmacy 24	No Vaccines	2 TO 8^0C	2	NO	YES	D Pharm And B Pharm
25	Pharmacy 25	Tetanus	2 TO 8^0 C	1	NO	YES	D Pharm
26	Pharmacy 26	Tetanus, Antirabies	2 TO 8^0C	2	NO	YES	D Pharm
27	Pharmacy 27	Tetanus	2 TO 8^0C	1	NO	YES	D Pharm

AVAILABILITY OF VACCINCES IN COMMUNITY PHARMACIES

Table 1: Different type of vaccines in various pharmacies.

Name of vaccine	Number of pharmacy
Tetanus	15
Anti Rabies	7
Adeno vaccines	2
Measles	4
MMR	6
Subunit type	5
Hepatitis B	3
Hepatitis A	2
No Vaccine	5

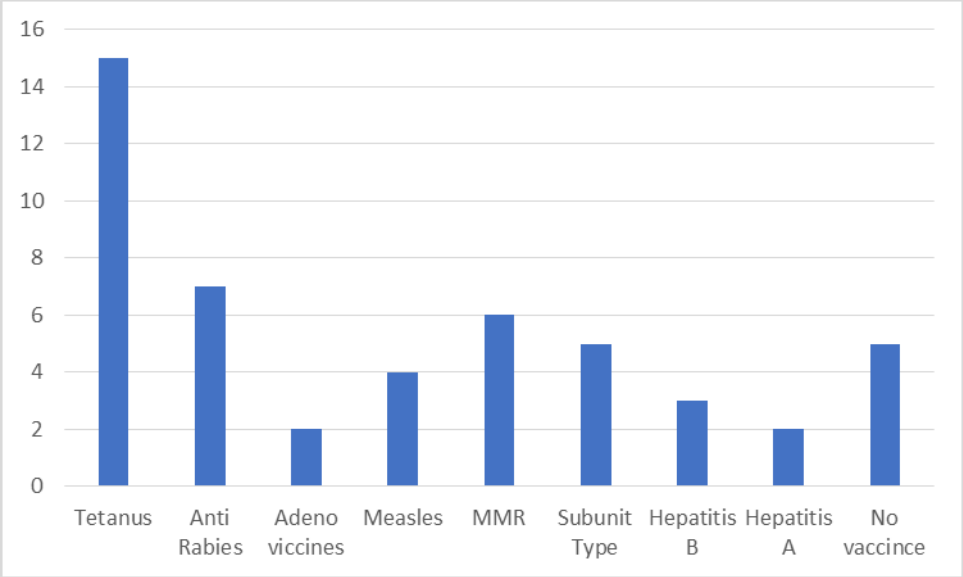

Figure No.2: Types of vaccine in various vaccine.

From our study, we observed that out of 27 pharmacies 15 pharmacies have tetanus vaccine, 7 pharmacies have antirabies vaccine, 2 pharmacies have adenovirus vaccine, 4 pharmacies

have measles, 6 pharmacies have MMR vaccine, 5 pharmacies have sub unit type vaccines, 3 pharmacies have hepatitis B and 2 pharmacies have hepatitis A.

From our study out of 27pharmacies about 5 pharmacies have no vaccine.

STORAGE CONDITION OF VACCINES IN COMMUNITY PHARMACIES

The storage conditions were assessed on the basis of availability of AC and cold chain facilities.

Table 2: Distribution of availability of AC in various pharmacies.

Availability Of Ac In Various Pharmacies	Number	Percentage (%)
Yes	6	22
No	21	77
Total	27	100

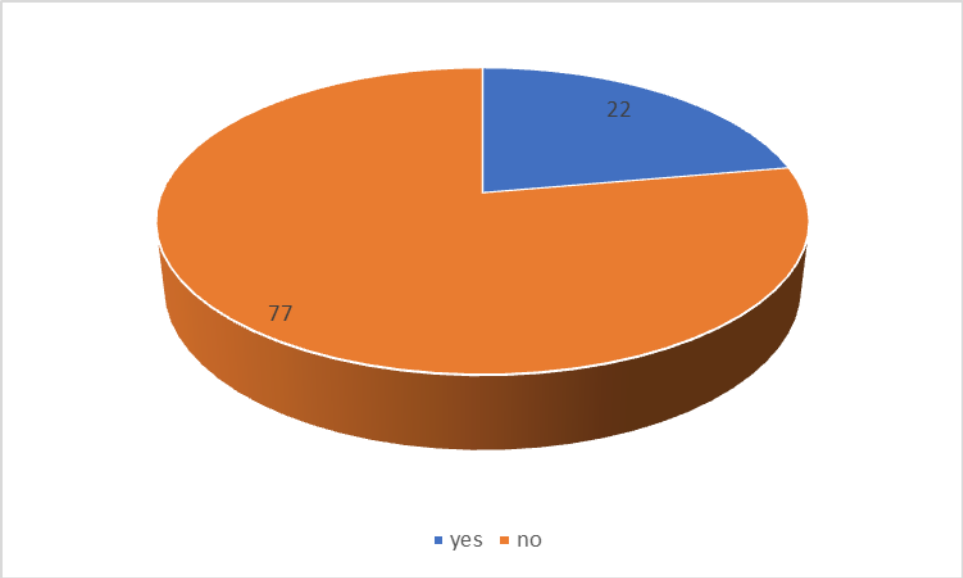

Figure No.3: Distribution of availability of AC in various pharmacies.

From our study we observed that, out of 27 pharmacies only 6 pharmacies which maintain the AC facilities for adequate storage of vaccines and about 21 pharmacies which doesn't maintain AC facilities.

Table 3: Distribution of availability of Cold Chain in various pharmacies.

Availability Of Cold Chain In Various Pharmacies	Number	Percentage (%)
Yes	23	85
No	4	14
Total	27	100

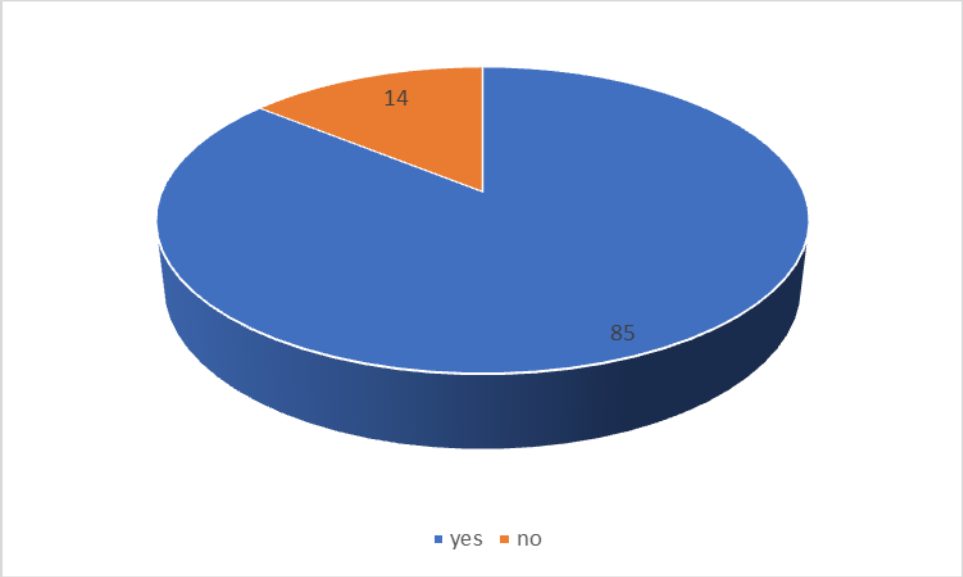

Figure No.4: Distribution of availability of cold chain in various pharmacies.

From our study we observed that out of 27 pharmacies about 85% pharmacies which maintain the cold chain for the storage of vaccines and 14 % pharmacies doesn't maintain the cold chain for storage of vaccines.

Number of pharmacies which maintain refrigerator facilities

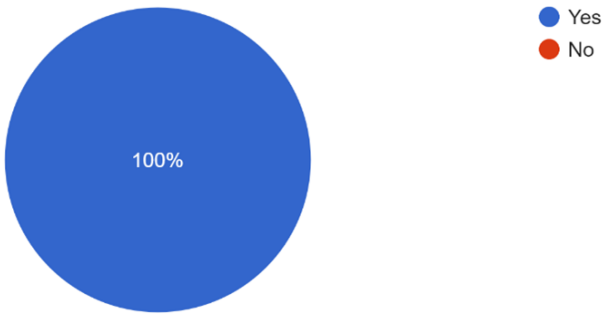

Figure No.5: Number of pharmacies which maintain refrigerator facilities.

From figure No.5, it was observed that out of 27 pharmacies all of the pharmacies maintained refrigerator facilities.

Table no. 4: Temperature maintained in various pharmacies.

Temperature Maintenance	Number of Pharmacy
2^0C	3
2 to 8^0C	24

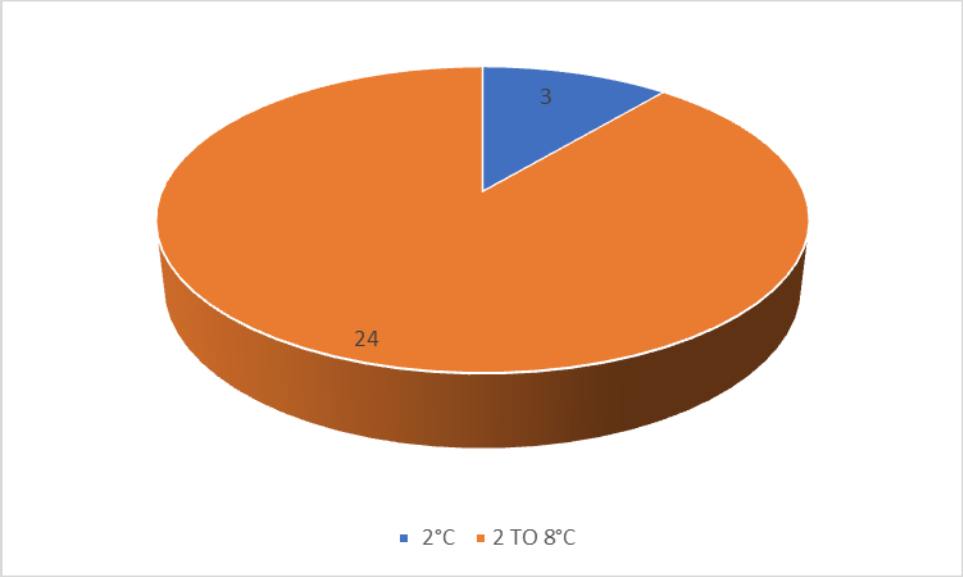

Figure No.6; Temperature maintained in various pharmacies.

From figure No.6, it was observed that 3 pharmacies were maintaining temperature at 2^0C and the rest of 24 pharmacies were maintaining temperature between 2 to 8^0C.

Table 5: Distribution of number of pharmacists in various pharmacies.

Number Of Pharmicist In Various Pharmacies	**Number**	**Percentage (%)**
One	10	37
Two	8	29
Three	6	22
Four	2	7
Five	1	3
Total	27	100

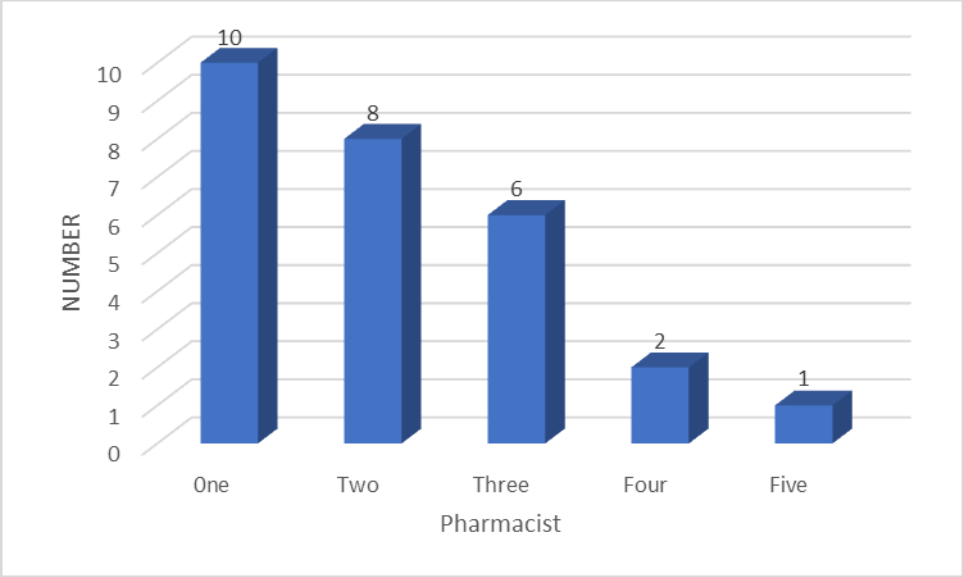

Figure No.7: Distribution of number of pharmacists in various pharmacies.

From our study, we observed that out of 27 pharmacies 10 pharmacies have one pharmacist, 8 pharmacies have 2 pharmacist, 6 pharmacies have 3 pharmacist, 2 pharmacies have 4 pharmacist and 1 pharmacy have 5 pharmacist.

Table 6: Distribution of qualification of pharmacists in various pharmacies,.

Qualification Of Pharmicist In Various Pharmacies	Number	Percentage (%)
D Pharm	21	77
D Pharm And B Pharm	4	17
B Pharm, M Pharm	2	8
Total	27	100

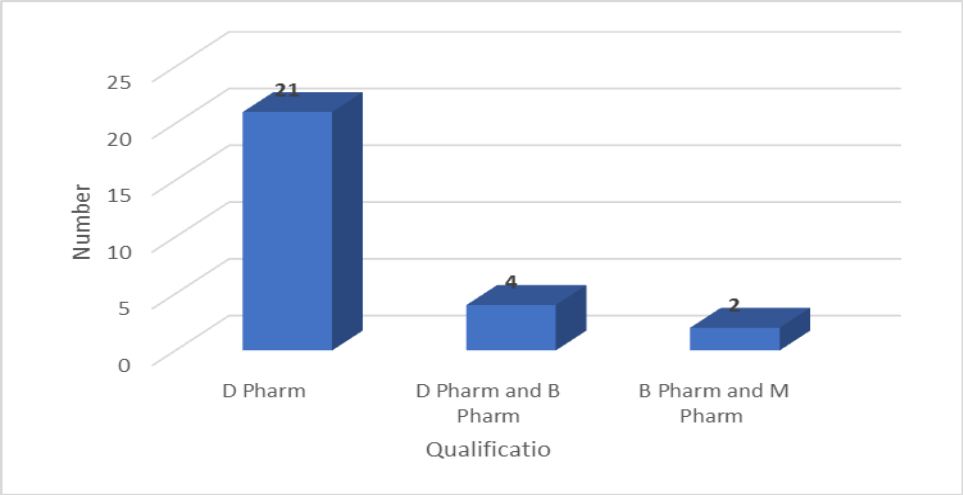

Figure No.8: Distribution of qualification of pharmacists in various pharmacIES.

From our study, we observed that out of 27 pharmacies about 21 pharmacies have the pharmacist qualification as D pharm, 4 pharmacies have the pharmacist qualification as D pharm and B pharm and 2 pharmacies have the qualification as B pharm and M pharm.

DISCUSSION

In developing countries like India, the majority of the population depends on public health care settings therefore, it is important to implement good drug-dispensing practices in public health care pharmacies to promote the safe and rational use of medicines. Personnel involved in dispensing medicines and vaccines are important. The facilities available to store and dispense medicines are important factors that influence dispensing pharmacy practices. Lack of dispensing facilities and dispensing of vaccines by an untrained person may lead to wastage and irrational dispensing of them. In this study, we found that in all surveyed pharmacies, vaccines were dispensed by experienced and registered pharmacists who were following good drug dispensing practices as well as the pharmacy practice regulations of India. From our survey we found that each pharmacies have eligible staffs for the purpose of dispensing vaccines. In most of the pharmacies the qualifications of staffs were either D pharm or B pharm. In a health care setting, pharmacists are mainly responsible for patient counseling regarding the safe use of vaccines.

Dinesh k Meena et al. conducted a study on Medicine storage and dispensing facilities in public healthcare pharmacies of Puducherry, India. This study includes the storage facilities available in community pharmacies, this helps us to understand more about the storage conditions needed. Similarly, from our study we understand that adequate storage facilities are maintained in pharmacies for the storage of vaccines.

Ram K Panika, Pankaj Prasad et al. conducted a study on evaluation of vaccine storage and cold chain management practices during intensified mission Indradhanush in community health centres of Tikamgarh district of Madhya Pradesh explained about proper vaccine storage and management of cold chain system is essential for immunisation. A pharmacy should have a sufficient storage area to store the adequate quantity of vaccines which should be separate from dispensing area. The storage area should be properly ventilated with refrigerator facilities. Keeping vaccines on the floor can lead to contaminations and breakage of vaccines. In our study, we found that 85% of pharmacies were maintaining cold chain, and 22% of pharmacies were equipped air conditioning facilities for storage of vaccines. A pharmacy needs to have a reception area and dispensing counter where a pharmacist can

dispense medicines including vaccines and counsel the patients. From our study, it was found that one qualified pharmacist is present in most of the pharmacies which is followed by two and three for the purpose of dispensing of vaccines. Almost all pharmacies maintain the refrigerator temperature at a range of 2 to 8^0C for the storage of vaccines. Some rare pharmacies maintain safety measures including temperature regulation, fire extinguisher, fire AC cylinder, water and sand.

Nugroho Agung Pambudi et al conducted a study on vaccine cold chain management and cold storage technology to address the challenges of vaccination programs. The aim of the study was to point out the major challenges of vaccination programs associated with vaccine cold chain management and cold storage facilities. Our study also indicated that proper maintenance of cold chain is important for vaccines storage.

Anika Thielmann et al conducted a study on visual inspection of vaccine storage condition in general practice: A study of 75 vaccine refrigerator. The aim of this publication is to assess the quality of vaccine refrigerator management in general practice. Our study also accomplished that the necessity of refrigerator in vaccine storage is inevitable.

Jaiprakash V Kokane, Pawan S Avhad conducted a study on role of pharmacist in healthcare system, according to the study the importance of pharmacist in healthcare system is explained. Pharmacist are the backbone in the healthcare system and also properly qualified and trained pharmacists are needed for this purpose. Our study also accomplished that adequately qualified pharmacists are involved in the dispensing of vaccines.

From our study we observed that adequate storage facilities must be available in pharmacies for vaccine storage. Negligence in the storage of vaccines may lead to its contamination which may further affects its efficacy as well as safety. Contaminated vaccines lack potency which may affect its therapeutic efficacy. Maintenance of cold chain is an important factor during the storage and dispensing of vaccines. Vaccines are one of the powerful tool that is essential to control the disease to a greater extent. Most of the life-threatening diseases were eradicated by the discovery of various vaccines. Vaccines are the lifesaving factor in most of the pandemic conditions. The impact that does by the vaccines are irreplaceable in this current scenario.

CONCLUSION

Vaccines are preparations that are used to stimulate the body's immune response against diseases. Vaccines are usually administered through needle injections, but some can be administered by mouth or sprayed into the nose. Vaccines help our body to create protective antibodies. By getting vaccinated, we can protect ourself and also avoid spreading preventable diseases to other people in our community. Disease burden due to vaccine preventable diseases is high. These diseases cause premature death, disability and malnutrition in young children. These vaccine preventable diseases can be prevented by vaccination and immunization.

In our study we demonstrate about the availability and storage of vaccines in community pharmacies. The vaccines available in the surveyed pharmacies are as follows: Tetanus(15), Anti rabies(7), Adeno vaccines(2), Measles(4), MMR(6), Subunit type(5), Hepatitis A(3), Hepatitis B(2) and 5 pharmacies have no vaccine.

The storage of vaccines is important, because improper storage can lead to contamination as well as attack by microbes. Most convenient way of storage for vaccines are in refrigerators. Maintenance of cold chain is an essential factor during the storage of vaccines. Vaccines should be stored in refrigerators at 2 to 8^0C.

In our study demonstrated that 27 samples are selected randomly from the accessible pharmacies from Parassala and the information's are collected from that pharmacies. From the data collected it was analysed that the distribution of air conditioner facilities is only 22%. The availability of cold chain maintained in various pharmacies is found to be 85%. According to the analysis from 27 pharmacies, majority of the pharmacies contain one pharmacist which is followed by two, three and four. From the study it was found out that out of 27 pharmacies 77% of pharmacist were qualified as D pharm, 17% were qualified by both D pharm and B pharm and 8% were qualified by both B pharm and M pharm. According to the study it was found that out of 27 pharmacies the refrigerator facilities including the maintenance of temperature{2 to 8^0C} are followed by all of them{100%}.

From our study we observed that adequate storage facilities must be available in pharmacies for vaccine storage. Negligence in the storage of vaccines may lead to its contamination which may further affects its efficacy as well as safety. Contaminated vaccines lack potency which may affect its therapeutic efficacy. Maintenance of cold chain is an important factor

during the storage and dispensing of vaccines. Vaccines are one of the powerful tool that is essential to control the disease to a greater extent. Most of the life-threatening diseases were eradicated by the discovery of various vaccines. Vaccines are the lifesaving factor in most of the pandemic conditions. The impact that does by the vaccines are irreplaceable in this current scenario.

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